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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID) Notice of Workshop

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health; the Food and Drug Administration (FDA); the Transformational Medical Technologies (TMT); and Biomedical Advanced Research and Development Authority (BARDA) are holding an Animal Model Development Workshop to explore the scientific and regulatory challenges of developing medical countermeasures (MCM) under the "Animal Rule" (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products). The goals of this workshop are to highlight the significant progress made in animal model development for MCMs, review recent case studies of products under development using animal models, and capture lessons learned to inform future animal model development efforts. In addition, the workshop will provide a forum to discuss current challenges and identify potential solutions or mitigation strategies.

DATES: The workshop will be held on September 17-18, 2012, at 8:00 a.m. EST. Participants must register by September 10, 2012.

ADDRESS: The workshop will be held at the NIH Natcher Conference Center, Building 45, 45 Center Drive, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: During the past decade, much progress has been made in the development of candidate medical products to prevent, treat, or diagnose the health effects of exposure to chemical, biological, radiological, and nuclear (CBRN) agents. With the convergence of scientific progress in medical countermeasures (MCMs) development, improvements in containment laboratory infrastructure, technological advances, and additional regulatory guidance, the stage is set for tangible progress in our ability to advance MCMs for CBRN agents. The effects of these efforts were evident in several recent FDA Advisory Committee meetings: anthrax vaccines (2010), smallpox therapeutics (2011), and plague antimicrobials (2012). Especially promising is the recent emphasis on cooperation among government agencies to leverage resources (scientific, human, and fiscal) in an effort to advance the development of animal models.

A solid regulatory and policy framework for fostering development of well-characterized animal models now exists. The Animal Rule laid the foundation for current efforts. FDA's draft guidance on Animal Models – Essential Elements to Address Efficacy Under the Animal Rule (January 2009) built upon that foundation and is currently undergoing substantial revision. More recently, the draft guidance on Qualification Process for Drug Development Tools (October 2010) outlined a concrete process for qualifying animal models. However, multiple scientific and regulatory challenges remain in animal model development.

This workshop is designed to explore the unique challenges being faced with the development of animal models for the evaluation of medical countermeasures for CBRN agents, including, but not limited to, the following crosscutting issues:

- Missing or limited data on the pathophysiological mechanisms of disease development in humans, especially with:
    - No recent outbreaks in humans, or outbreaks occur only in remote locations with limited infrastructure and capabilities
    - Altered virulence or other properties of the natural agent
    - A difference between the normal route of exposure and the route likely to be used in a bioterrorism event
- Use of mortality as an endpoint, particularly when case fatality of naturally occurring disease in humans is less than 100 percent
- Incorporation and importance of biomarkers
- Correlates of disease progression
- Definition of supportive care and implementation given:
    - Adequate veterinary care
    - Intervention necessary for model development
    - Intervention to mimic human clinical care
- Acceptability of euthanasia criteria and early study endpoints
- Reproducibility of models

If you are interested in attending, please register at the following link: https://respond.niaid.nih.gov/conferences/AMDW/Pages/default.aspx by September 10, 2012. There is no registration fee for the workshop. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please

contact Dr. Judy Hewitt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the workshop.

FOR FURTHER INFORMATION CONTACT: Dr. Judy Hewitt, Office of Biodefense Research Affairs, Division of Microbiology and Infectious Diseases, NIAID, at telephone 301-402-4197 or telefax 301-480-1263 or e-mail AMworkshopSep2012@mail.nih.gov (Subject line: Animal Model Workshop).

Dated: July 18, 2012

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